

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Prasco, LLC,

Plaintiff,

v.

Case No. 1:06cv313

Medicis Pharmaceutical Corp., *et al.*,

Judge Michael R. Barrett

Defendants.

ORDER

This matter is before the Court upon Defendants Medicis Pharmaceutical Corporation (“Medicis”) and Imaginative Research Associates, Inc.’s (“Imaginative”) Motion to Dismiss and Motion to Dismiss the Amended Complaint. (Docs. 15, 19) Also before the Court is Plaintiff Prasco’s Response in Opposition to Defendants’ Motion to Dismiss the Amended Complaint, and Defendants’ Reply thereto. (Doc. 20, 21) In addition, the Parties have provided supplemental briefing on the application of the United States Supreme Court’s recent decision in *MedImmune, Inc. v. Genetech, Inc., et al*, 127 S.Ct. 764 (January 9, 2007). (Docs. 25, 28, 31)

I. FACTUAL AND PROCEDURAL BACKGROUND

Defendant Medicis manufactures and markets the product TRIAZ. This product has four patents associated with it: U.S. Patent Nos. 5,254,334 (‘334); 5,409,706 (‘706); 5,632,996 (‘996); and 5,648,389 (‘389). Medicis is the assignee for the ‘389 patent and is the licensee for the ‘334, ‘706, and ‘996 patents. Defendant Imaginative is the assignee

for the '334, '706, and '996 patents, and licenses these patents to Medicis.¹ TRIAZ is an acne cleanser containing benzoyl peroxide in the concentrations 3%, 6%, and 9%. Medicis commercially markets TRIAZ as being covered by the patents-in-suit, and labels the packaging and labeling with these patent numbers.

On May 5, 2006, Prasco filed its Complaint for declaratory judgment, seeking a declaration that its product OSCION has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the patents-in-suit. OSCION is a generic acne cleanser also containing benzoyl peroxide in the concentrations 3%, 6%, and 9%. OSCION is designed as a fully substitutable generic alternative to TRIAZ and intended to compete directly with it. Prior to the filing of the declaratory action, Prasco had not begun to market OSCION, and Defendants had no knowledge of Prasco's product. (Doc. 15, Ex. 1, Brandon Hokenstad Decl. ¶ 3; Doc. 15, Ex. 2, Mohan Vishnupad Decl. ¶¶ 4-5)

On July 25, 2006, Defendants filed their Motion to Dismiss Prasco's Complaint. (Doc. 15). Prasco did not respond to this motion, but instead filed an Amended Complaint on August 18, 2006. (Doc. 17) The Amended Complaint states that on June 14, 2006, Prasco commercially launched OSCION. (Doc. 17 ¶ 29). Prasco alleges that on July 28, 2006, it provided Medicis and Imaginative with a sample of OSCION, its related labeling, and an ingredient list. (Id. ¶ 31) Prasco also alleges that on July 28, 2006 it requested from Medicis and Imaginative a covenant not to sue relating to the '334, '706, '996, and '389 patents; but Medicis and Imaginative have refused this request. (Id. ¶¶ 35-38)

On September 9, 2006, Defendants filed their Motion to Dismiss the Amended

¹The parties dispute whether Medicis, as licensee, would have the right to enforce the three Imaginative patents. Based on the Court's analysis, *infra*, the Court finds it unnecessary to reach this issue.

Complaint. (Doc. 19) This matter is now ripe for review.

II. ANALYSIS

A. Motion to Dismiss Standard

Defendants bring their motions to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1). Defendants assert there is no "actual case or controversy" and therefore this court lacks subject matter jurisdiction.

The Sixth Circuit has distinguished between facial and factual attacks among motions to dismiss for lack of subject matter jurisdiction pursuant to Rule 12(b)(1). *Pritchard v. Dent Wizard Intern. Corp.*, 210 F.R.D. 591, 592 (S.D.Ohio 2002). A facial attack on the subject matter jurisdiction alleged by the complaint merely questions the sufficiency of the pleading. *Ohio Nat. Life Ins. Co. v. U.S.*, 922 F.2d 320, 325 (6th Cir. 1990). Defendants are bringing a factual attack. A factual attack is "not a challenge to the sufficiency of the pleading's allegations, but a challenge to the factual existence of subject matter jurisdiction." *United States v. Ritchie*, 15 F.3d 592, 598 (6th Cir. 1994). Therefore, this Court must "weigh the conflicting evidence to arrive at the factual predicate that subject matter jurisdiction exists or does not exist." 922 F.3d at 325. The Court may allow affidavits, documents and even a limited evidentiary hearing to resolve disputed jurisdictional facts. *Id.*

B. The Reasonable Apprehension of Suit Test

The Declaratory Judgment Act provides that, "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). The Supreme Court has explained that under

the Act:

The controversy must be definite and concrete, touching the legal relations of parties having adverse legal interests. It must be a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.

Aetna Life Ins. Co v. Haworth, 300 U.S. 227, 240-41 (1937) (citations omitted). However, the Supreme Court has not precisely defined what type of controversies satisfy this standard. See *MedImmune*, 127 S.Ct. at 771 ("*Aetna* and the cases following it do not draw the brightest of lines between those declaratory-judgment actions that satisfy the case-or-controversy requirement and those that do not.")

The Federal Circuit, in determining when a "case" or "controversy" exists in a patent declaratory judgment action, developed the "reasonable apprehension of suit" test:

There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993).

In *MedImmune*, the Supreme Court stated that the Federal Circuit's "reasonable apprehension of suit" test contradicts earlier Supreme Court precedent. 127 S.Ct. at 774, n.11. However, the Court only held that the "reasonable apprehension of suit" test is not the appropriate test to determine subject matter jurisdiction for a declaratory action in the context of a patent licensee paying royalties under protest. *Id.* The Court's decision may call into doubt the use of the "reasonable apprehension of suit" test, but it did not overrule the line of cases that rely upon the "reasonable apprehension of suit" test outside of this

factual scenario.² Therefore, Federal Circuit precedent establishing the "reasonable apprehension of suit" test as the determinative test when evaluating subject matter jurisdiction for a declaratory judgment involving potential infringement, remains binding upon this Court. *Accord BridgeLux, Inc. v. Cree, Inc.*, No. 06-6495, 2007 WL 521237, at *2 (N.D.Cal. Feb. 15, 2007) (slip op.); *WS Packaging Group, Inc. v. Global Commerce Group, LLC*, No. 06-674, 2007 WL 205559, at *3 (E.D. Wisc. Jan. 24, 2007) (slip op.); *but see Rite-Hite Corp. v. Delta T Corp.*, 2007 WL 725327, *8 (E.D. Wisc. March 7, 2007) (slip op.) ("[t]he Supreme Court has called into serious question the continued viability of the Federal Circuit's 'reasonable apprehension of suit' test in patent declaratory judgment actions. In light of such fact, this court is reluctant to employ that test in ruling on the defendants' motions to dismiss. Indeed, to do so would be to ignore the Supreme Court's clear signal that such test has a limited future life expectancy."); *Highway Equipment Company, Inc. v. Cives Corp.*, 2007 WL 689766, *2 (N.D. Iowa March 7, 2007) (slip op.) (explaining that in *MedImmune*, the Supreme Court abrogated the reasonable-apprehension test).

C. Factual Basis for Jurisdiction

Defendants argue that Prasco must rely upon the facts that existed at the time it filed its original Complaint in order to support subject matter jurisdiction. The Court disagrees.

Federal Rule of Civil Procedure 15(a) provides that "[a] party may amend the party's pleading once as a matter of course at any time before a responsive pleading is served."

²The Federal Circuit Court of Appeals has not yet addressed the effect that the Supreme Court's decision in *MedImmune* has had upon the reasonable-apprehension test.

Accordingly, Prasco's amendments were "as a matter of course" because Defendants have not yet served a responsive pleading.

In addition, Federal Rule of Civil Procedure 15(d) provides that a party may "serve a supplemental pleading setting forth transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented." Rule 15(d) would permit a party to supplement his or her complaint in order to state a claim and avoid dismissal. See Fed.R.Civ.P. 15(d), Advisory Committee Notes (1963) (indicating that Rule 15(d) was intended to overcome "the rigid and formalistic view that where the original complaint fails to state a claim upon which relief can be granted, leave to serve a supplemental complaint must be denied"); see also 28 U.S.C. § 1653 ("Defective allegations of jurisdiction may be amended, upon terms, in the trial or appellate courts"). Other district courts have held that when a plaintiff files an amended complaint, the date of that second filing becomes the controlling date for determining subject matter jurisdiction. *Pharmachemie B.V. v. Pharmacia S.p.A.*, 934 F.Supp. 484, 489 (D.Mass. 1996), citing *Millipore Corp. v. University Patents, Inc.*, 682 F.Supp. 227, 233 (D.Del. 1987); *Northern Telecom Inc. v. Wang Laboratories, Inc.*, 543 F.Supp. 1026, 1028 (D.Mass.1982). Therefore, the Court will determine subject matter jurisdiction based on the facts alleged in the Amended Complaint.

D. Subject Matter Jurisdiction

A party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy. *Cardinal Chemical Co. v. Morton Intern., Inc.*, 508 U.S. 83, 95 (1993), citing *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-241 (1937).

At issue is whether Prasco satisfies the first prong of the reasonable apprehension

of suit test.³ “Although the best evidence of a reasonable apprehension of suit comes in the form of an express threat of litigation, an express threat is not required.” *Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1254 (Fed.Cir. 2002). There has been no allegation of an express threat of litigation by Defendants. Where a defendant's conduct, including its statements, falls short of an express charge, one must consider the “totality of the circumstances” in determining whether that conduct meets the first prong of the test. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988).

Prasco contends that the following facts, when viewed in their totality, create a reasonable apprehension of an infringement suit by Defendant Imaginative: (1) Imaginative has sought patent protection for its ‘334, ‘706, and ‘996 patents, and licenses these patents to Medicis; and (2) Imaginative has refused to provide Prasco with a covenant not to sue related to these patents.

Owning and licensing a patent alone or in combination does not constitute conduct creating a “reasonable apprehension of suit.” More is required for an actual controversy than the existence of an adversely held patent. *Capo, Inc. v. Dioptics Med. Prods.*, 387 F.3d 1352, 1355 (Fed. Cir. 2004).

Although a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination, this factor is not dispositive. *BP Chemicals Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 980 (Fed. Cir. 1993). Plaintiff has not cited case law which would support a finding of a “reasonable apprehension of suit” based solely on the refusal to sign a covenant not to sue. Based on the foregoing, the Court concludes that Prasco

³There appears to be no dispute that Prasco meets the second prong.

has not alleged conduct sufficient to objectively establish a "reasonable apprehension of suit" by Defendant Imaginative.

In regards to Defendant Medicis, Prasco contends that the following facts, when viewed in their totality, create a reasonable apprehension of an infringement suit: (1) Medicis has sought patent protection for its '389 patent and is the licensee of Imaginative's '334, '706, and '996 patents; (2) Medicis marks its acne cleanser product as being "covered" by the patents-in-suit; (3) Medicis has previously sued Prasco for patent infringement; (4) Medicis has made statements indicating a willingness to aggressively pursue patent rights; and (5) Medicis has refused to provide Prasco with a covenant not to sue related to these patents.

The Court is not persuaded that these facts establish a "reasonable apprehension of suit" by Defendant Medicis. First, as explained above, owning and licensing a patent alone does not constitute conduct creating a "reasonable apprehension of suit."

Second, the fact that Medicis has marked its product as being "covered" by the patents-in-suit has no bearing on the issue at hand. The patent marking statute, 35 U.S.C.A. § 287(a) requires that a patentee must provide notice to a potential infringer before damages for infringement will accrue. The fact that Medicis may at some undetermined point in time choose to file an infringement suit against an unspecified potential infringer does not lead to a "reasonable apprehension of suit" by Prasco. See *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005) (holding that the listing of patent FDA's Orange Book, without more, should not be construed as blanket threat to potential infringers).

Third, even when viewed in combination with the above, Medicis' history of litigation

is not sufficient to create a reasonable apprehension of suit. On October 27, 2005 Medicis filed a complaint against Prasco and another generic company in federal court in Arizona seeking a declaration that Prasco's product PRASCION infringed another of Medicis' patents. (Doc. 17, ¶ 40) During the litigation Medicis stated that it would continue to "vigorously pursue" the issue "through additional legal avenues." (Id.) Prasco has alluded to other prior litigious conduct by Medicis, but with no specificity. (Doc. 20, at 11).

In cases where courts have found prior litigation sufficiently threatening, either (1) the defendant referenced that litigation in some communication to the plaintiff, *see, e.g., Arrowhead*, 846 F.2d at 733, 737; *Ivoclar Vivadent, Inc. v Hasel*, No. 02-CV-0316E(F), 2003 WL 21730520, at *5 (W.D.N.Y. June 30, 2003) (unpublished), or (2) there was ongoing litigation between the parties over a series of closely related patents involving the same technology, *see, e.g., Goodyear*, 824 F.2d at 955.

Here, there is no evidence that Medicis ever referenced the litigation in its communications with Prasco; and Prasco has not alleged that the Arizona litigation involved the same technology as the patents-in-suit in this action. While Prasco has grouped both products into a category of Medicis' "core products," Prasco has not identified any relationship between the patents. Defendants state that the patent in the Arizona litigation recites a different pharmacological agent than the patents at issue here. (Wortzman Decl. ¶¶ 10-13; Vishnupad Decl. ¶¶ 9-11) In addition, the Court notes that Medicis' statements to the effect that it would continue to "vigorously pursue" the issue "through additional legal avenues" was within the context of responding to the denial of a preliminary injunction, and was not in reference to enforcement of the patents which are the subject of this litigation. Therefore, this statement is distinguishable from cases which

have held that statements evidencing an intent to enforce patents create "reasonable apprehension." See, e.g., *Plumtree Software, Inc. v. Datamize, LLC*, 473 F.3d 1152, 1158 (Fed. Cir. 2006); *Mobil Oil Corp. v. Advanced Environmental Recycling Technologies, Inc.*, 1996 WL 325081, *2 (Fed. Cir. 1996) (unpublished).

Finally, Prasco asks the Court to consider Medicis' refusal to concede noninfringement or grant a covenant not to sue relating to these patents. As explained above, a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination, but is not dispositive. The Court finds that the present situation is different from that in *Kos Pharms., Inc. v. Barr Labs., Inc.*, 242 F.Supp.2d 311 (S.D.N.Y.), a case cited by Prasco. In *Kos*, the court found that the failure to provide a covenant not to sue properly added grounds to support a reasonable apprehension of suit. *Id.* at 317. The court explained that other pending litigation between the parties involved patents that were very similar to the patents involved in the declaratory action, which demonstrated that the risk of future litigation was real. *Id.*; see also *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333-34 (Fed. Cir. 2005) (defendant's refusal to give covenant not to sue, combined with history of asserting patent rights against other alleged infringers, did not create reasonable apprehension of suit). The Court concludes that based on the facts alleged, Defendants' refusal to provide a covenant-not-to-sue or conceded noninfringement is not dispositive.

When considering the "totality of the circumstances," Prasco has not alleged conduct sufficient to objectively establish a "reasonable apprehension of suit" by

Defendants.⁴ Therefore, Defendants Medicis Pharmaceutical Corporation and Imaginative Research Associates, Inc.'s Motion to Dismiss the Amended Complaint (Docs. 19) is **GRANTED**; and Defendants' Motion to Dismiss (Doc. 15) is **DENIED as MOOT**. This matter shall be **CLOSED and STRICKEN** from the docket of this Court.

IT IS SO ORDERED.

/s/ Michael R. Barrett
Michael R. Barrett, Judge
United States District Court

⁴The Court finds that even if the reasonable apprehension of suit test is no longer good law after the Supreme Court's decision in *MedImmune*, there is no actual case or controversy present based upon the facts in the record. In *MedImmune*, the Supreme Court explained that their earlier decisions in declaratory judgment actions had required that:

the dispute be "definite and concrete, touching the legal relations of parties having adverse legal interests"; and that it be "real and substantial" and "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what that law would be upon a hypothetical state of facts." ... "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

Medimmune, 127 S.Ct. at 771 (citations omitted); see also *Rite-Hite*, 2007 WL 725327 at *8. Applying these principles, the Court finds that there is no definite and concrete dispute that touches the legal relations of these parties. Medicis has not stated that its patents have been infringed; and before this litigation commenced, Defendants were not aware of Prasco's product. In addition, Medicis' refusal to provide a covenant-not-to-sue or concede non-infringement is not the type of "substantial controversy" upon which to base this Court's jurisdiction.